

Atty Dkt. No.: CLON-094
USSN: 10/806,930

REMARKS

In view of the following remarks, the Examiner is requested to withdraw the rejections and allow Claims 1-10 and 17, as well as newly presented Claims 18-26, the only claims pending and currently under examination in this application.

Claim 1 has been amended to remove the "optional" language. Newly presented Claim 18 finds support in originally presented Claims 1 and 2, and newly presented Claims 19-26 find support in originally presented Claims 3 to 10. As the above amendments introduce no new matter to the application, their entry by the Examiner is respectfully requested.

It is noted that the above amendments have been made solely in order to expedite allowance of the present application, and should in no way be construed as an acquiescence by the Applicants with the Office with respect to any rejection appearing in the Office Action. The Applicants expressly reserve the right to pursue the claims of their original scope and format in a continuation application.

Claims 1-10 and 17 have been rejected under 35 C.F.R. § 112, second ¶. In view of the above amendment to Claim 1, this rejection may be withdrawn.

Claims 1-10 and 17 have been rejected under 35 U.S.C. § 101 for assertedly reading on a product of nature because the claims do not recite the phrase "isolated and purified." Claim 1 recites in part:

**A nucleic acid encoding a polypeptide product comprising a
first and second chromo/fluorescent domain.....**

As such, the claimed nucleic acids must encode proteins that have two distinct domains, where the domains are independently colored or fluorescent domains. Such

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nucleic acids are "tandem" nucleic acids, where an illustration of such a nucleic acid is found in Figure 6A. The Applicants are not aware of this particular structure being a naturally occurring structure. Instead, naturally occurring chromo or fluorescent proteins have a single colored or fluorescent domain. Since the claims are not directed to nucleic acids that only have a single colored or fluorescent domain that arises from the interaction of two or more amino acid residues, but instead are directed to nucleic acids that include at least two distinct colored or fluorescent domains, the claims clearly do not read on a product of nature. As such, this rejection may be withdrawn.

Next, Claims 1-10 and 17 have been rejected under 35 U.S.C. § 102(b) over Ward et al., WO 01,32688.

It is first noted that this reference was actually published on May 10, 2001. It is only a reference as of its publication date since the application was filed prior to November 29, 2000. As the present application is entitled to its priority date of October 12, 2001, this reference only qualifies as a reference to this application under 35 U.S.C. § 102(a).

Turning now to the reference itself, in making this rejection the Examiner points to the following section at page 29:

- 15 The GFP coding sequence can also be used as a reporter protein in transgenic cells or organisms. In a preferred embodiment of the invention, a *Renilla* GFP coding sequence is operably fused to the coding sequence of a protein of interest, an appropriate promoter region and termination region, and transformed into a cell. In this manner, the localization of a protein of interest can be
- 20 determined *in vivo*, using the fluorescent properties of the fused GFP protein. Fusions of this nature can localize proteins to specific structures of the cell, such as the cytoskeleton, plasma membrane, nucleus, mitochondria, secretory pathway, and can also be used to study, *in vivo*, dynamic changes in the distribution and/or turnover of proteins within the cell, or within an organism. Such fusion proteins
- 25 can also be used as an indicator of protein-protein interactions: the interaction a GFP fusion protein and a fusion protein comprised of a second fluorescent protein, i.e. anthozoan luciferase, may be detected by the resonance transfer of energy from one fluorescent molecule to the other.

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The Ward disclosure is solely directed to a new fluorescent protein. As can be seen in the above passage, when Ward discusses luciferase, it is solely in the context of using two physically distinct nucleic acids in a protein-protein, i.e., bait-prey, interaction assay. In this application, Ward teaches use of a first nucleic acid that encodes a first fusion protein of a bait domain fused to a single fluorescent protein domain, and a second nucleic acid that encodes a second fusion protein of a prey domain fused to a single luciferase protein. At no point does Ward teach a single nucleic acid that encodes a protein having two distinct colored or fluorescent domains, i.e., a first domain encoding a fluorescent protein and a second domain encoding a luciferase.

Because Ward fails to teach a single nucleic acid that includes at least two distinct domains encoding distinct fluorescent or chromoproteins, Ward fails to anticipate the Claims 1-10 and 17 and this rejection may be withdrawn.

Next, Claims 1-10 and 17 have been provisionally rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over Claims 1-12 and 19 of copending application serial no. 10/757,356. In making this rejection, the Examiner points to the section of the 10/757,356 application which teaches that "the proteins of interest are colored or fluorescent and this feature arises from the interaction of two or more residues of the protein." In response, it is respectfully submitted that the Examiner has incorrectly equated the term "residue" in the copending application with "domain" in the claims of the present application. As pointed out above, the claims of the present application are directed to nucleic acids that include sequences that give rise to two distinct colored or fluorescent domains. This structure is not the same as two residues that give rise to a single colored or fluorescent domain. Accordingly, this provisional rejection may be withdrawn.

Finally, Claims 1-10 and 17 have been provisionally rejected under the judicially

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created doctrine of obviousness type double patenting as being unpatentable over Claims 1-24 and 30 of copending application serial no. 10/006,922. In making this rejection, the Examiner points to the section of the 10/006,922 application which teaches that "the proteins of interest are colored or fluorescent and this feature arises from the interaction of two or more residues of the protein." In response, it is respectfully submitted that the Examiner has incorrectly equated the term "residue" in the copending application with "domain" in the claims of the present application. As pointed out above, the claims of the present application are directed to nucleic acids that include sequences that give rise to two distinct colored or fluorescent domains. This structure is not the same as two residues that give rise to a single colored or fluorescent domain. Accordingly, this provisional rejection may be withdrawn.

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CONCLUSION

In view of the above remarks, this application is considered to be in good and proper form for allowance and the Examiner is respectfully requested to pass this application to issuance.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815.

Respectfully submitted,

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